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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,386	10/16/2001	James F. Zucherman	KLYC-01055US1	4255

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,386

Applicant(s)

ZUCHERMAN ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 42-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-41, drawn to a dilator, classified in class 606, subclass 191.
 - II. Claims 42-26, drawn to a method of dilating a ligament, classified in class 606, subclass 99.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the curved dilator can be used for other purposes, such as dilating ligaments other than ligaments of the spine.

3. During a telephone conversation with Sheldon Meyer on 03/20/03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 42-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1,2,7,8,13-16,21,22,28,29,34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,361,766 to Nichols et al.

Nichols discloses a device that has an elongated body (20) with a tapered curved tip (22) on one end and a handle (10) on the opposite end, as most clearly illustrated in Figure 2. The device is used in procedures related to spinal implants. As shown more clearly in Figure 4, the tip of the device is clearly curved at an angle relative to the body, because an angle is any angle from 0 to 360 degrees. The curved tip has a first diameter that gradually increases in one dimension to a second diameter. The body of the device also includes markers (28) that determine the size of an opening (column 2, lines 48-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-6,9-12,17-20,23-26,30-33,and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al.

Nichols includes all the limitations of the claims, but does not explicitly state the size of the curved tip dilator. The device is sized for being inserted into areas of the spine. It would have been an obvious matter of design choice to form the device to have the dimensions set forth in the claims, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols in view of US Patent No. 5,836,948 to Zucherman et al.

Nichols, as modified above, includes all the limitations of claim 27, except for kit containing four dilators of increasing size. Zucherman teaches that tapered curved dilators (see Figure 39) can be provided in kits of a plurality of dilators, with each one being slightly bigger than the one before. Zucherman goes on to explain that the smallest dilator would be used first followed by the next size of dilator, so that the opening is gradually enlarged (column 9, lines 45-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a the modified Nichols dilator as a set of dilators differing in size, as taught by Zucherman, as this equips a surgeon with the proper tools to progressively enlarge on opening.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,334,194 to Mikhail discloses a device with a tapered curved tip that is used to

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enlarge openings in ligaments. US 5,891,47 to Moskovitz et al. discloses curved probe with a tapered curved tip (Figure 8). US 5,569,300 to Redmon discloses a ligament dilator that has a curved, tapered tip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 305-3590 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

sw

March 21, 2003

sw

Sarah K Webb
Examiner
Art Unit 3731


DAVID O. REIP
PRIMARY EXAMINER

for
Michael Milano
Supervisory Patent Examiner
Art Unit 3700